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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

EXAMINER	
COTTON, ABIGAIL MANDA	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,134	BURNETT ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-42,44-72 and 74-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-42,44-72 and 74-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 20, 2006 has been entered.

Claims 39-42, 44-72 and 74-84 are pending in the application and are being examined on the merits herein.

Applicant's arguments regarding the rejections of the claims have been fully considered but they are not persuasive. The claims are being rejected as follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 84 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter that was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the specification does not provide support for the recitation that the composition does not contain propylene carbonate, as recited in the claim. The specification teaches that various penetration enhancers/solvents may be provided, such as ethanol and propylene glycol, the specification is silent as to the use or non-use of the specific compound that is propylene carbonate. Accordingly, as the specification does not provide adequate support for the composition as claimed, the claim is rejected under 35 U.S.C. 112, first paragraph as having impermissible new matter. Cancellation of the new matter is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-42, 44-62, 64, 66-71, 74-75, 77-80 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,993,787 to Sun et al.

Sun et al. teaches anhydrous topical preparations with good physical stability and excellent cosmetic attributes comprising propylene carbonate; one or more short chain alcohols and/or glycols, such as ethanol, isopropanol, propylene glycol, polyethylene glycol, etc; glycerol (glycerine); and an active ingredient (see Abstract, in particular.) The topical preparations are formulated as, e.g. gels (see column 3, lines 14-19, in particular.) Active ingredients are selected from antifungal agents, such as miconazole nitrate, ketoconazole, etc. (see column 6, lines 1-12, in particular.) Additional components, such as pigments, ascorbic acid, BHT, chelating agents, hydroxypropyl cellulose, etc. are taught to be useful therein (see column 4, lines 9-13, column 8, lines 20-65 and column 9, lines 17-28, in particular.) Emollients such as Arlamol E® (PPG-15 Stearyl Ether) are also taught to be useful therein (see column 10, lines 61-67 and column 16, lines 19-37, in particular.) Antifungal agents (miconazole nitrate) are exemplified in concentrations of 2%; propylene glycol is exemplified at 20% BHT is exemplified at 0.05%; glycerol is exemplified at 20%; chelating agents are taught at 0.1-10%; PPG-15 stearyl ether is exemplified at 2%; and ethanol is exemplified at 55.87$ by weight (i.e., about 50% by weight, as recited in the claims) (see column 8, lines 42-49 and column 10, line 32 through column 11, line 3, in particular.) The treatment of athlete's foot (tinea pedis), ring worm (tinea corporis), jock itch (tinea cruria) and the administration to human skin is taught (see column 2, lines 38-58 and column 9, line 60 through column 10, line 5, in particular.) Use of compositions against *T. rubrum*, specifically, is also taught (see column 12, line 46 through column 14, line 5, in

particular.) Sun et al. does not specifically exemplify the combinations as herein envisioned.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a composition comprising the glycols and alcohols as herein envisioned because Sun et al. teaches that one or more of such glycols and/or alcohols may be used in the anhydrous preparations described therein. Furthermore, Sun et al. specifically exemplifies combinations of alcohols and/or glycols in the anhydrous preparations. It would have been obvious to one of ordinary skill in the art to utilize ketoconazole as the antifungal agent in the compositions exemplified in Sun et al. because Sun et al. envisioned miconazole nitrate and ketoconazole to be interchangeable agents therein. Accordingly, one of skill in the art would have been motivated to formulate the composition as claimed in order to prepare a topical antifungal composition with good physical stability and excellent cosmetic attributes suitable for the treatment of athlete's foot, ring worm and jock itch, as taught by Sun et al.

It is noted that the solubility of the ketoconazole is a function of the amounts of components in the system. Accordingly, since the concentrations of components as claimed are the same as taught by the prior art, the degree of solubilization of ketoconazole would be the same in the prior art composition as the composition claimed.

It is noted that the components useful herein are disclosed, generally, as being useful in the invention of Sun et al. Accordingly, absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art to optimize the concentrations of said components to arrive at the concentrations as herein envisioned. "[W]here the general conditions of a claim are disclosed in the prior art, it is note inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220, F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the recitation that the composition "does not contain a retinoid or a steroid" as recited in claim 39, it is noted that Sun et al. teaches that the active ingredient can be an antifungal, and exemplifies compositions containing an antifungal agent (e.g. miconazole nitrate) that do not contain a steroid or a retinoid (see column 10, lines 30-68, in particular.) Thus, such compositions that do not contain a steroid or a retinoid are considered to be obvious over Sun et al.

Claims 63, 65 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al, as applied to claims 39-42, 44-62, 64, 66-71, 74-75, 77-80 and 83 above, in view of U.S. Patent No. 5,208,257 to Kabara.

Sun et al. is applied as disclosed above. Sun et al. teaches that the use of a chelating agent increasing the wrinkle regulating benefits of the compositions disclosed

therein (see column 8, lines 33-41, in particular.) Sun et al. does not specifically teach the use of citric acid.

Kabara teaches a topical antimicrobial composition (see abstract, in particular.) Chelating agents, such as citric acid, are taught to be useful herein (see column 7, lines 64 through column 8, line 7, in particular.)

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize citric acid in a composition of Sun et al. because (1) both Sun et al. and Kabara are directed to antimicrobial compositions; (2) Sun et al. teaches the addition of a chelating agent increases the wrinkle regulating benefits of the compositions disclosed therein; and (3) Kabara teaches citric acid as a chelating agent. One would have been motivated to add citric acid to the composition of Sun et al. in order to increase the wrinkle regulating benefits of the composition, as taught by Sun et al.

Claims 76 and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. as applied to claims 39-42, 44-62, 64, 66-71, 74-75, 77-80 and 83 above, in view of U.S. Patent No. 5,231,087 to Thornfeldt.

Sun et al. is applied as discussed above. The reference does not specifically teach a method of treating seborrheic dermatitis.

Thornfeldt teaches that *P. ovale* has been shown to play a significant role in seborrheic dermatitis. It is also taught that ketoconazole is known for the treatment of seborrheic dermatitis (see column 2, liens 44-60, in particular.)

It would have been obvious to one of ordinary skill in the art to utilize the composition rendered obvious by Sun et al. in the treatment of *P. ovale* related skin disorder seborrheic dermatitis in humans because (1) the compositions of Sun et al. are disclosed to comprise antifungal agents such as ketoconazole, and (2) Thornfeldt teaches that ketoconazole is capable of treating seborrheic dermatitis. One would have been motivated to treat seborrheic dermatitis with such a composition because, as taught by Thornfeldt, ketoconazole has been reported to improve or clear seborrheic dermatitis lesions in about 75% of patients (see column 2, lines 44-60, in particular.)

Claims 39-42, 44-51, 55-61, 63, 65-71 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,476,852 to Gerard F.M.J. Cauwenbergh, issued December 19, 1995, in view of U.S. Patent No. 5,110,809 to Wang et al, issued May 5, 1992.

Cauwenbergh teaches a method of topically treating subjects suffering from acne, hyperkeratotic dermatoses and photo-aging of the skin, by administering to said subjects an effective amount of an antifungal ketoconazole, which is an imidazole

compound (see abstract and ketoconazole chemical structure in column 1, lines 45-65, in particular.) Cauwenbergh teaches that it has been unexpectedly discovered that ketoconazole alone and when administered topically can effectively be used in the treatment of humans suffering from dermatological conditions (see column 1, lines 30-40, in particular.) Cauwenbergh also teaches that, besides the use of ketoconazole alone, it may also be applied with an appropriate retinoid (see column 4, lines 15-35, in particular), and thus teaches that the retinoid is an optional component for efficacy of the composition. Accordingly, Cauwenbergh teaches a topically applicable composition containing ketoconazole, and that does not contain a retinoid, and thus teaches part (e) of claims 39 and 84

Cauwenbergh further teaches that suitable skin-acceptable carriers for such compositions include gels (see column 2, lines 55-68, in particular), and thus teaches the composition can be formulated as a gel as recited in the claims.

Cauwenbergh does not specifically teach providing an anhydrous gel carrier with propylene glycol and ethanol, as recited in claims 39 and 84.

Wang et al. teaches a stable anhydrous gel formulation for topical antifungal use (see abstract, in particular.) Wang et al. teaches that formulation comprising imidazoles are stabilized by providing a specific vehicle (see column 5, lines 50-68, in particular.) Wang et al. teaches that the anhydrous vehicle comprises a co-solvent system having a

lower alkanol in combination with a dihydroxy alcohol (see column 6, lines 1-35, in particular.) Wang et al. teaches that lower alkanols can include ethanol, propanol, isopropanol, and the like (see column 6, lines 1-30, in particular), as in part (a) of claims 39 and 84. Wang et al. also teaches that the dihydroxy alcohols can comprise propylene glycol (see column 6, lines 1-20, in particular), as in part (b) of claims 39 and 84.

Wang et al. further teaches that the anhydrous gel composition can comprise other conventional components such as glycerin as an emollient (see column 8, line 23-40, in particular), and thus teaches part (d) of claims 39 and 84. Wang et al. also teaches that the anhydrous gel composition can comprise a gelling agent such as hydroxypropylcellulose (see column 7, line 65 through column 8, line 6, in particular.) Regarding part (c) of claims 39 and 84, it is noted that Cauwenbergh further teaches that the composition having the antifungal ketoconazole can comprise a thickening agent, such as polyethylene glycol, hydroxypropylcellulose, and others (see column 3, lines 30-45, in particular), and thus teaches that polyethylene glycol can be provided to thicken a topical composition and is interchangeable with the hydroxypropylcelluose as taught by Wang et al, and thus teaches providing the component as recited in part (c) of claims 39 and 84.

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the ketoconazole of Cauwenbergh in the

anhydrous gel carrier of Wang et al, and including the other conventional components as taught by Wang et al, because Cauwenbergh teaches that ketoconazole, and imidazole antifungal agent, can be topically administered in a gel carrier, and Wang et al. teaches that the anhydrous gel provides a suitable stable carrier for imidazole antifungal agents that is also suitable for topical application. Thus, one of ordinary skill in the art would have been motivated to provide the anhydrous propylene glycol/ethanol gel carrier of Wang et al. for the ketoconazole treatment compound of Cauwenbergh, with the expectation of providing a stable formulation of the imidazole antifungal, ketoconazole, that is suitable for topical application.

It would furthermore have been obvious to combine the thickener polyethylene glycol as taught by Cauwenbergh with the anhydrous gel formulation as taught by Wang et al, because Cauwenbergh teaches that the ketoconazole formulations can comprise the thickener and that propylene glycol is interchangeable with hydroxypropylcellulose as a thickener, and Wang et al. teaches that the anhydrous gel can comprise other conventional additives, including hydroxypropyl cellulose as a gelling agent. Thus, one of ordinary skill in the art would have found it obvious to provide the polyethylene glycol of Cauwenbergh in the anhydrous gel formulation of Cauwenbergh and Wang et al., with the expectation of providing a suitable additive to the composition that can provide a desired thickness of the composition, and that is interchangeable with the gelling agent as taught by Wang et al.

Regarding the recitation that the composition "does not contain a retinoid or a steroid" as recited in claims 39 and 84, and furthermore that the composition does not contain propylene carbonate, as recited in claim 84, it is noted that Cauwenbergh teaches that ketoconazole can be used by itself, i.e. without steroids or retinoids, to provide treatment, and neither Cauwenbergh nor Wang et al. teach that propylene carbonate is necessary for the composition. Accordingly, the teachings of Cauwenbergh and Wang et al. render obvious the anhydrous gel formulation of ketoconazole that has parts (a)-(e) as in claims 39 and 84.

Regarding claim 40, is it considered since the combined teachings of Cauwenbergh and Wang et al. renders the claimed composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely the solubilization of ketoconazole, are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product. It is furthermore noted that Wang et al. teaches dissolving the imidazoles in the solvent system (see column 6, lines 1-15, in particular.)

Regarding claims 41-42, Cauwenbergh et al. teaches that a suitable amount of the ketoconazole can be from 0.1-10%, such as from 0.2-2.5% (see column 3, lines 48-53, in particular), and thus teaches a range that overlaps with that being claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of ketoconazole provided in the composition, according to the guidance provided by Cauwenbergh and Wang et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 44-45, Cauwenbergh et al. teaches that the thickener, such as polyethylene glycol, can be provided in various amounts according to the vehicle provided (see column 3, lines 45-66, in particular.) Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of polyethylene glycol provided in the composition, according to the guidance provided by Cauwenbergh and Wang et al, to provide a composition having desired properties, such as a desired thickness. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the amount of propylene glycol as recited in claims 46-47, Wang et al. teaches that the dihydroxy alcohol can be present in an amount of from 0 to 45% by weight (see column 6, lines 15-20, in particular), and thus teaches a range that overlaps with that claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of propylene glycol provided in the composition, according to the guidance provided by Cauwenbergh and Wang et al, to provide a composition having desired properties, such as a desired solvent system. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding the amount of glycerin provided and the emollient as recited in claims 48-51, Wang et al. teaches that emollients such as glycerin can be provided in an amount of up to 30%, which overlaps with the range as recited. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of glycerin provided in the composition, according to the guidance provided by Cauwenbergh and Wang et al, to provide a composition having desired properties, such as desired emollient properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 55-58, Wang et al. also teaches that the anhydrous gel composition can comprise a gelling agent such as hydroxypropylcellulose (see column 7, line 65 through column 8, line 6, in particular), and thus teaches providing the viscosifier, as recited in the claims. Wang et al. further teaches that the gelling agent can comprise form 0.1 to 5% of the composition (see column 8, lines 1-10, in particular), and thus teaches a range that overlaps with that recited in claims 56 and 58. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of gelling agent provided in the composition, according to the guidance provided by Cauwenbergh and Wang et al, to provide a composition having desired properties, such as desired gelling consistency. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 59 and 61, Cauwenbergh also teaches that the ketoconazole compositions can comprise citric acid as a buffer or as an antioxidant (see column 3, lines 40-46, in particular). Wang et al. also teaches that the anhydrous gel composition can comprise antioxidants (see column 8, lines 35-40, in particular). Accordingly, it is considered that one of ordinary skill in the art would furthermore have been motivated to provide the citric acid of Cauwenbergh in the anhydrous gel composition because Wang

et al. teaches that the anhydrous gel composition can comprise conventional additives such as antioxidants, and Cauwenbergh et al. teaches that citric acid can be provided as an antioxidant in topical compositions having ketoconazole. Thus, one of ordinary skill in the art would have been motivated to provide the citric acid in the anhydrous gel composition with the expectation of providing a suitable antioxidant in the composition.

Regarding the amount of the citric acid provided, as recited in claims 60, 63 and 65, Wang et al. teaches that antioxidants can make up to 2% by weight of the composition (see column 8, lines 35-40, in particular), which overlaps with the amount as claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of antioxidant provided in the composition, according to the guidance provided by Cauwenbergh and Wang et al, to provide a composition having desired properties, such as desired antioxidant properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 66 and 68, Wang et al. also teaches that the anhydrous gel composition can comprise antioxidants such as BHT (butylated hydroxytoluene) (see column 8, lines 35-40, in particular). Regarding the amount of the butylated hydroxytoluene provided, as recited in claims 67 and 69-70 Wang et al. teaches that

antioxidants can make up to 2% by weight of the composition (see column 8, lines 35-40, in particular), which overlaps with the amount as claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of antioxidant provided in the composition, according to the guidance provided by Cauwenbergh and Wang et al, to provide a composition having desired properties, such as desired antioxidant properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claim 71, Wang et al. teaches that the anhydrous gel composition can comprise fragrances and dyes (colorants) (see column 9, lines 35-40, in particular.)

Claims 62 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,476,852 to Gerard F.M.J. Cauwenbergh, issued December 19, 1995, in view of U.S. Patent No. 5,110,809 to Wang et al, issued May 5, 1992, as discussed for claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and further in view of U.S. Patent No. 4,214,000 to Christopher M. Papa, issued July 22, 1980.

Cauwenbergh and Wang et al. are applied as discussed for claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and teach the anhydrous gel composition containing ketoconazole, ethanol, propylene glycol, polyethylene glycol, and glycerin, as recited in

the claims. Cauwenbergh and Wang et al. also teach that antioxidants can be provided in the composition.

Cauwenbergh and Wang et al. do not specifically teach that the anhydrous gel composition contains ascorbic acid, as recited in the claims.

Papa teaches that a topical composition can comprise antioxidants, including ascorbic acid (see abstract and column 3, lines 55-65, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the ascorbic acid of Papa into the anhydrous gel composition of Cauwenbergh and Wang et al, because Cauwenbergh and Wang et al. teach the topical composition can comprise an antioxidant, and Papa teaches that ascorbic acid is an antioxidant that is suitable for use in a topical composition. Thus, one of ordinary skill in the art would have been motivated to provide the antioxidant ascorbic acid in the composition of Cauwenbergh and Wang et al, with the expectation of providing an antioxidant in the composition suitable for topical use.

Regarding the amount of the ascorbic acid provided, as recited in claims 62 and 64, Wang et al. teaches that antioxidants can make up to 2% by weight of the composition (see column 8, lines 35-40, in particular), which overlaps with the amount as claimed. Furthermore, it is considered that one of ordinary skill in the art at the time

the invention was made would have found it obvious to vary and/or optimize the amount of antioxidant provided in the composition, according to the guidance provided by Cauwenbergh, Wang et al, and Papa to provide a composition having desired properties, such as desired antioxidant properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claims 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,476,852 to Gerard F.M.J. Cauwenbergh, issued December 19, 1995, in view of U.S. Patent No. 5,110,809 to Wang et al, issued May 5, 1992, as discussed for claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and further in view of U.S. Patent No. 5,292,530 to McCrea et al, issued March 8, 1994.

Cauwenbergh and Wang et al. are applied as discussed for claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and teach the anhydrous gel composition containing ketoconazole, ethanol, propylene glycol, polyethylene glycol, and glycerin, as recited in the claims. Cauwenbergh and Wang et al. also teach that the composition can contain an emollient, as discussed above,

Cauwenbergh and Wang et al. do not specifically teach that the anhydrous gel composition contains PPG-15 stearyl ether, as recited in the claims.

McCrea et al. teaches that emollients may be used to reduce or eliminate phase separation in anhydrous, topically effective composition (abstract; col. 4, lines 43-50.) McCrea et al. specifically teaches that PPG-15 stearyl ether would be an effective emollient therein (col. 16, lines 42-44.)

It would have been obvious to one of ordinary skill in the art to add the emollient PPG-15 stearyl ether of McCrea et al. to the composition of Cauwenbergh and Wang et al. because (1) all of the McCrea et al, Cauwenbergh and Wang et al. compositions are for topical use, and teach the incorporation of emollients and (2) the McCrea et al. and the Cauwenbergh and Wang et al. compositions are anhydrous. One would have been motivated to add PPG-15 stearyl ether to the compositions of Cauwenbergh and Wang et al. because (1) it reduces or eliminates phase separation of a topical composition, as taught by McCrea et al, and (2) provides the desired emollient effect as taught by Cauwenbergh and Wang et al, and thus one of ordinary skill would have had a reasonable expectation of formulating a composition having reduced phase separation and that has desired emollient skin soothing benefits. Accordingly, the teachings of Cauwenbergh, Wang et al, and McCrea et al. render obvious the compositions of claim 52.

Regarding claims 53-54, it is noted that McCrea et al. teaches that PPG-15 stearyl ether can be provided as an emollient, as discussed above, and that Wang et al.

teaches that the emollients can be in an amount of up to 30% by weight in the composition (see column 8, lines 30-35, in particular), which overlaps with the ranges as claimed. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the PPG-15 stearyl ether emollient provided in the composition, according to the guidance provided by Cauwenbergh, Wang et al. and McCrea et al, to provide a composition having desired properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,476,852 to Gerard F.M.J. Cauwenbergh, issued December 19, 1995, in view of U.S. Patent No. 5,110,809 to Wang et al, issued May 5, 1992, as discussed for claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and further in view of U.S. Patent No. 4,214,000 to Christopher M. Papa, issued July 22, 1980, and U.S. Patent No. 5,292,530 to McCrea et al, issued March 8, 1994.

Cauwenbergh and Wang et al. are applied as discussed for claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and teach an anhydrous gel composition for topical delivery comprising propylene glycol, polyethylene glycol, glycerin, ethanol, ketoconazole, hydroxypropyl cellulose, butylated hydroxytoluene and citric acid, as

discussed above, and that does not contain a retinoid or a steroid. Thus, Cauwenbergh and Wang et al. teach a composition having the components (a)-(e), (g), and (i)-(j), as recited in the claims. Cauwenbergh and Wang et al. also teach that antioxidants and emollients can be provided in the composition, as discussed above.

Cauwenbergh and Wang et al. do not specifically teach that the anhydrous gel composition contains ascorbic acid, as recited in the claims.

Papa teaches that a topical composition can comprise antioxidants, including ascorbic acid (see abstract and column 3, lines 55-65, in particular.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to incorporate the ascorbic acid of Papa into the anhydrous gel composition of Cauwenbergh and Wang et al, because Cauwenbergh and Wang et al. teach the topical composition can comprise an antioxidant, and Papa teaches that ascorbic acid is an antioxidant that is suitable for use in a topical composition. Thus, one of ordinary skill in the art would have been motivated to provide the antioxidant ascorbic acid in the composition of Cauwenbergh and Wang et al, with the expectation of providing an antioxidant in the composition suitable for topical use.

Cauwenbergh, Wang et al and Papa do not specifically teach that the anhydrous gel composition contains PPG-15 stearyl ether, as recited in the claims.

McCrea et al. teaches that emollients may be used to reduce or eliminate phase separation in anhydrous, topically effective composition (abstract; col. 4, lines 43-50.) McCrea et al. specifically teaches that PPG-15 stearyl ether would be an effective emollient therein (col. 16, lines 42-44.)

It would have been obvious to one of ordinary skill in the art to add the emollient PPG-15 stearyl ether of McCrea et al. to the composition of Cauwenbergh, Wang et al. and Papa because (1) both of the McCrea et al. and the combined Cauwenbergh, Wang et al. and Papa compositions are for topical use, and teach the incorporation of emollients and (2) the McCrea et al. and the Cauwenbergh, Wang et al. and Papa compositions are anhydrous. One would have been motivated to add PPG-15 stearyl ether to the compositions of Cauwenbergh, Wang et al. and Papa because (1) it reduces or eliminates phase separation of a topical composition, as taught by McCrea et al, and (2) provides the desired emollient effect as taught by Cauwenbergh, Wang et al. and Papa, and thus one of ordinary skill would have had a reasonable expectation of formulating a composition having reduced phase separation and that has desired emollient skin soothing benefits. Accordingly, the teachings of Cauwenbergh, Wang et al, Papa and McCrea et al. render obvious the composition of claim 72.

Claims 74-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,476,852 to Gerard F.M.J. Cauwenbergh, issued December 19, 1995,

in view of U.S. Patent No. 5,110,809 to Wang et al, as applied to claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and further in view of U.S. Patent No. 5,231,087 to Thornfeldt, issued July 27, 1993.

Cauwenbergh and Wang et al. are applied as discussed for claims 39-42, 44-51, 55-61, 63, 65-71 and 84 above, and teach an anhydrous gel composition comprising of ketoconazole and the other ingredients as claimed.

The references do not specifically teach the methods of claims 74-83, specifically treating fungal disorders associated with T. rubrum or P. ovale, and specifically seborrheic dermatitis, as recited in claims 76 and 80.

Thornfeldt teaches that P. Ovale has been shown to play a significant role in seborrheic dermatitis in humans. It is also known that ketoconazole is known for the treatment of seborrheic dermatitis (see abstract and col. 2, lines 44-60.)

It would have been obvious to one of ordinary skill in the art to utilize the composition taught by Cauwenbergh and Wang et al. in a treatment of the P. ovale related skin disorder seborrheic dermatitis in humans because (1) Cauwenbergh and Wang et al. teach that such compositions are suitable for the treatment of the skin disorders, and (2) Thornfeldt teaches that ketoconazole is capable of treating seborrheic dermatitis in humans. One would have been motivated to treat seborrheic dermatitis

with such a composition because, as taught by Thornfeldt, ketoconazole has been reported to improve or clear seborrheic dermatitis lesions in about 75% of patients (col. 2, lines 44-60), and thus one of ordinary skill would have a reasonable expectation of success in providing a treatment for the seborrheic dermatitis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39-42, 44-72 and 84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 8-16, 22 and 25-26 of U.S. Patent No. 6,238,683 ('683). Although the conflicting claims are not

identical, they are not patentably distinct from each other because '683 claims an anhydrous composition comprising 1-50% propylene glycol, 10-80% PEG and glycerin, an aqueous vehicle and ketoconazole (see claim 1.) The medicaments are solubilized (see claim 2.) The vehicle is selected from an alcohol (see claim 3.) Emollients, chelating agents, pH adjusted (e.g. citric acid, ascorbic acid, etc), antioxidants (e.g. BHT), gelling agents, viscosifiers (e.g. hydroxypropyl cellulose), colorants, etc. are also claimed (see claims 8-11.) (For the claimed concentrations, see claims 12-16, 22 and 25-26.

Claims 74-83 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3, 8-16, 22 and 24-26 of U.S. Patent No. 6,238,683 ('683) in view of Thornfeldt (U.S. Patent No. 5,231,087.) For a discussion of the claimed compositions, see the rejection above. Claim 24 of '683 claims a method of administration of the composition disclosed in '683. Thornfeldt teaches that *P. ovale* has been shown to play a significant role in seborrheic dermatitis. It is also taught that ketoconazole is known for the treatment of seborrheic dermatitis (see column 2, lines 44-60, in particular.) Accordingly, it would have been obvious to one or ordinary skill in the art to treat seborrheic dermatitis with a composition comprising an agent known in the art to be useful in the treatment thereof.

Claims 39-42, 44-72 and 74-84 are provisionally rejected under the judicially created doctrine of obviousness-type double-patenting as being unpatentable over

claims 48-53, 56-62 and 86-118 of copending Application No. 09/562,376 ('376). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '376 are substantially similar to those of the instant invention. The only difference between '376 and the instant invention is that '376 lacks the limitation that a retinoid and steroid are not present, and recites that the composition "consists of" the components recited in the claims. Furthermore, there is no indication in '376 that a retinoid or steroid need be added. Accordingly, it would have been obvious to one of ordinary skill in the art to prepare the claimed composition and to utilize it in the same manner as claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed November 20, 2006 have been fully considered but they are not persuasive.

In particular, Applicant's argue that based on the description in Sun et al, teaches "literally hundreds of compositions" would be possible, because Sun et al. teaches numerous different alcohols and/or glycols that could be used, and thus Applicants conclude that there would be no motivation for one of ordinary skill in the art to select

the particular claimed composition from the list of components described by Sun et al. (see paragraph bridging pages 8-9 of Remarks submitted on November 20, 2006.) The Examiner respectfully disagrees. Sun et al. teaches that the anhydrous compositions generally contain the alcohols and/or glycols, and one or more of glycerin and an active ingredient (see abstract, in particular.) With regards to the alcohols and glycols, Sun et al. exemplifies compositions containing ethanol and propylene glycol, as recited in parts (a)-(b) of claim 39, for example, and exemplifies the antifungal agent miconazole nitrate therewith, which is taught as being interchangeable with ketoconazole (see column 10, lines 30-68 and column 6, lines 1-15, in particular.) Thus, Sun et al. guides one towards providing an alcohol and/or glycol component having ethanol and propylene glycol, and one or more of glycerin and an active agent where the active agent can be ketoconazole. The only remaining component of claim 39 that is not particularly picked out by Sun et al. for exemplification, is polyethylene glycol. However, Sun et al. teaches that polyethylene glycol can also be suitable used as the alcohol and/or glycol, and is interchangeable with ethanol and propylene glycol (see abstract, in particular.) Accordingly it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to provide the claimed combination of components as taught by Sun et al, with the expectation of providing a suitable topical composition for delivering the ketoconazole active ingredient.

Applicants further argue that Sun et al. exemplifies compositions having ethanol in a higher amount (e.g., 55.87%) than that claimed, and thus does not teach or suggest

the claimed compositions. The Examiner notes that the amount of 55.87% is considered to be within the claimed range of from about 1 to about 50% as recited in the claims. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of the ethanol provided in the composition, according to the guidance provided by Sun et al, to provide a composition having desired properties, such as desired topical carrier properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

The declaration filed under 37 C.F.R. 1.132 and signed by Cauwenbergh has been considered but is not persuasive to remove the prior art of record. In particular, the Examiner notes that evidence of unexpected results is required to be reasonably commensurate in scope with the claimed invention. See, e.g., In re Kulling, 897 F.2d 1147, 1149, 14 USPQ2d 1056, 1058 (Fed. Cir. 1990); In re Grasselli, 713 F.2d 731, 743, 218 USPQ 769, 777 (Fed. Cir. 1983). Applicant argues the benefits of the anhydrous composition "The ketoconazole product" that consists of the particular components in the particular amounts by weight as listed on page 3 of the declaration. In contrast, the claims are directed to a composition which comprises the components (a)-(e), and thus can also contain components other than those listed in the table for the "ketoconazole product," such as the propylene carbonate or menthol of Sun et al. Thus,

the results as described correspond to a composition that is not commensurate in scope with that claimed.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMC

SREENI PADMANABHAN
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